Medicare and the SGR Formula

Medicare has come under increasing fire from those who think the federal government is spending too much on it as well as from those who think the government is being too cheap.

Fast Facts

- According to government estimates, spending on Medicare will rise to $524 billion by 2011. That number, driven in part by the addition of the Part D prescription drug benefit, makes the program a hot topic in Congress. Page 12.
- The initial idea behind the Sustained Growth Rate (SGR) formula was to link Medicare spending increases to growth in the economy plus a couple of extra percentage points to allow for inflation. But by the time the legislation passed, the inflation adjuster had gotten stripped out. The result was a formula that didn’t reflect the changes in the cost of providing medical care. Page 13.
- Pay-for-performance seems to be an idea that is here to stay. But efforts won’t succeed without input from physicians. Page 28.

Medicare was established in 1965 to provide health coverage for all seniors 65 and older. In 1972, the program was expanded to include people with permanent disabilities regardless of their age. Medicare currently provides health insurance for nearly 43 million people; in 2006, the program cost the federal government $331 billion.

According to government estimates, spending on Medicare will rise to $524 billion by 2011. That number, driven in part by the addition of the Part D prescription drug benefit, makes the
Discover Levemir®: a long-acting basal insulin with a light touch

Levemir: for your patients who need a safe and effective way to improve A1C control

With proven reductions in A1C and FPG levels over time, Levemir can help your patients get to goal with up to 24 hours of glycemic control. Patients with diabetes can experience a consistent blood glucose response from injection to injection. Less weight gain was observed with Levemir in 12 of 12 clinical trials.* And Levemir is available in the Levemir® FlexPen®. FlexPen® is the world’s #1 selling prefilled insulin pen. So start your patients with diabetes on Levemir, and help them experience the light side of basal insulin.

Levemir is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

Important safety information
Levemir should not be diluted or mixed with any other insulin preparations.

Levemir is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

Hypoglycemia is the most common adverse effect of all insulin therapies, including Levemir. As with other insulins, the timing of hypoglycemic events may differ among various insulin preparations. Glucose monitoring is recommended for all patients with diabetes. Any change of insulin dose should be made cautiously and only under medical supervision. Concomitant oral antidiabetes treatment may require adjustment.

Levemir is not to be used in insulin infusion pumps. Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia in patients being switched to Levemir from other intermediate or long-acting insulin preparations. The dose of Levemir may need to be adjusted in patients with renal or hepatic impairment.

Other adverse events commonly associated with insulin therapy may include injection site reactions (on average, 3% to 4% of patients in clinical trials) such as lipodystrophy, redness, pain, itching, hives, swelling, and inflammation.

*Whether these observed differences represent true differences in the effects of Levemir and NPH insulin is not known, since these trials were not blinded and the protocols (eg, diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences in weight has not been established.

Reference: 1. IMS Health, IMS MIDAS [12 months ending September 2005].

Please see brief summary of Prescribing Information on adjacent page. FlexPen and Levemir are registered trademarks of Novo Nordisk A/S.

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Levemir®
insulin detemir (rDNA origin) injection
Lighter years ahead
Levemir®
insulin detemir (rDNA origin) injection

Rx ONLY
BRIEF SUMMARY. Please see package insert for prescribing information.

INDICATIONS AND USAGE
LEVEMIR is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

CONTRAINDICATIONS
LEVEMIR is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

WARNINGS
Hyposglycemia is the most common adverse effect of insulin therapy, including LEVEMIR. As with all insulins, the timing of hyposglycemia may differ among various insulin formulations.

Glucose monitoring is recommended for all patients with diabetes.

LEVEMIR is not to be used in insulin infusion pumps.

Any change of insulin dose should be made cautiously and only under medical supervision. Changes in insulin strength, timing of dosing, manufacturer, type (e.g., regular, NPH, or insulin analogs), species (animal, human), or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage. Concomitant oral antidiabetic treatment may need to be adjusted.

PRECAUTIONS
General
Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. The first symptoms of hyperglycemia usually occur gradually over a period of hours to days. They include nausea, vomiting, drowsiness, flushed dry skin, dry mouth, increased urination, thirst and loss of appetite as well as aceton breath. Untreated hyperglycemic events are potentially fatal.

LEVEMIR is not intended for intravenous or intramuscular administration. The prolonged duration of activity of insulin detemir is dependent on injection into subcutaneous tissue. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia. Absorption after intramuscular administration is both faster and more extensive than absorption after subcutaneous administration.

LEVEMIR should not be diluted or mixed with any other insulin preparations (see PRECAUTIONS, Mixing of Insulins).

Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Lipodystrophy and hypersensitivity are among potential clinical adverse effects associated with the use of all insulins.

As with all insulin preparations, the time course of LEVEMIR action may vary in different individuals or at different times in the same individual and is dependent on site of injection, blood supply, temperature, and physical activity.

Adjustment of dosage of any insulin may be necessary if patients change their physical activity or their usual meal plan.

Hyposglycemia
As with all insulin preparations, hypoglycemic reactions may be associated with the administration of LEVEMIR.

Hyposglycemia is the most common adverse effect of insulins. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, use of medications such as beta-blockers, or intensified diabetes control (see PRECAUTIONS, Drug Interactions).

Such situations may result in severe hypoglycemia (and, possibly, loss of consciousness) prior to patients’ awareness of hypoglycemia.

The time of occurrence of hypoglycemia depends on the action profile of the insulin used and may, therefore, change when the treatment regimen or timing of dosing is changed. In patients being switched from other intermediate or long-acting insulin preparations to once- or twice-daily LEVEMIR, dosages can be prescribed on a unit-to-unit basis; however, as with all insulin preparations, dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia.

Renal Impairment
As with other insulins, the requirements for LEVEMIR may need to be adjusted in patients with renal impairment.

Hepatic Impairment
As with other insulins, the requirements for LEVEMIR may need to be adjusted in patients with hepatic impairment.

Injection Site and Allergic Reactions
As with any insulin therapy, lipodystrophy may occur at the injection site and delay insulin absorption. Other injection site reactions with insulin therapy may include redness, pain, itching, hives, swelling, and inflammation. Continuous rotation of the injection site within a given area may help to reduce or prevent these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions may require discontinuation of LEVEMIR.

In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique.

Systemic allergy: Generalized allergy to insulin, which is less common but potentially more serious, may cause rash (including pruritus) over the whole body, shortness of breath, wheezing, reduction in blood pressure, rapid pulse, or sweating. Severe cases of generalized allergy, including anaphylactic reaction, may be life-threatening.

Intercurrent Conditions
Insulin requirements may be altered during intercurrent conditions such as illness, emotional disturbances, or other stresses.

Information for Patients
LEVEMIR must only be used if the solution appears clear and colorless with no visible particles. Patients should be informed about potential risks and advantages of LEVEMIR therapy, including the possible side effects. Patients should be offered continued education and advice on insulin therapies, injection technique, life-style management, regular glucose monitoring, periodic glycosylated hemoglobin testing, recognition and management of hypo- and hyperglycemia, adherence to meal planning, complications of insulin therapy, timing of dosage, instruction for use of injection devices and proper storage of insulin. Patients should be informed that frequent, patient-performed blood glucose measurements are needed to achieve effective glycemic control to avoid both hyperglycemia and hypoglycemia. Patients must be instructed on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, or skipped meals. Refer patients to the LEVEMIR “Patient Information” circular for additional information.

As with all patients who have diabetes, the ability to concentrate and/or react may be impaired as a result of hyposglycemia or hyperglycemia.

Patients with diabetes should be advised to inform their health care professional if they are pregnant or are contemplating pregnancy (see PRECAUTIONS, Pregnancy).

Laboratory Tests
As with all insulin therapy, the therapeutic response to LEVEMIR should be monitored by periodic blood glucose tests. Periodic measurement of HbA1c is recommended for the monitoring of long-term glycemic control.

Drug Interactions
A number of substances affect glucose metabolism and may require insulin dose adjustment and particularly close monitoring.

The following are examples of substances that may reduce
the blood-glucose-lowering effect of insulin: corticosteroids, diazepans, sympathomimetic agents (e.g., epinephrine, alpha-blocking agents), isoniazid, phenothiazine derivatives, somatostatin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives). The following are examples of substances that may increase the blood-glucose-lowering effect of insulin and susceptibility to hypoglycemia: oral antidiabetic drugs, ACE inhibitors, disopyramide, furosemide, MAO inhibitors, propylene glycol, salicylates, somatostatin analog (e.g., octreotide), and sulfonylurea antibiotics.

Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood-glucose-lowering effect of insulin. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia. In addition, under the influence of sympatholytic medicinal products such as beta-blockers, clonidine, guanethidine, and reserpine, the signs of hypoglycemia may be reduced or absent.

The results of in-vitro and in-vivo protein binding studies demonstrate that there is no clinically relevant interaction between insulin detemir and fatty acids or other protein bound drugs.

Mixing of Insulins
If LEVEMIR is mixed with other insulin preparations, the profile of action of one or both individual components may change. Mixing LEVEMIR with insulin aspart, a rapid acting insulin analog, resulted in about 40% reduction in AUC_<sub>0</sub>-<sub>inf</sub> and C<sub>max</sub> for insulin aspart compared to separate injections when the ratio of insulin aspart to LEVEMIR was less than 50%.

LEVEMIR should NOT be mixed or diluted with any other insulin preparations.

Carcinogenicity, Mutagenicity, Impairment of Fertility Studies: 2-year carcinogenicity studies in animals have not been performed. Insulin detemir tested negative for genotoxic potential in the in-vitro reverse mutation study in bacteria, human peripheral blood lymphocyte chromosome aberration test, and the in-vivo mouse micronucleus test.

Pregnancy: Teratogenic Effects: Pregnancy Category C
In a fertility and embryonic development study, insulin detemir was administered to female rats before mating, during mating, and throughout pregnancy at doses up to 300 nmol/kg/day produced numbers of litters with visceral anomalies. Doses up to 900 nmol/kg/day (approximately 135 times the recommended human dose based on AUC) were given to rabbits during organogenesis. Drug-dose related increases in the incidence of females with gall bladder abnormalities such as small, bloated, bifurcated and missing gall bladders were observed at a dose of 900 nmol/kg/day. The rat and rabbit embryofetal development studies that included concurrent human insulin control groups indicated that insulin detemir and human insulin had similar effects regarding embryotoxicity and teratogenicity.

Nursing Mothers
It is unknown whether LEVEMIR is excreted in significant amounts in human milk. For this reason, caution should be exercised when LEVEMIR is administered to a nursing mother. Patients with diabetes who are lactating may require adjustments in insulin dose, meal plan, or both.

Pediatric Use
In a controlled clinical study, HbA<sub>1c</sub>, concentrations and rates of hypoglycemia were similar among patients treated with LEVEMIR and patients treated with NPH human insulin.

Geriatric Use
Of the total number of subjects in intermediate and long-term clinical studies of LEVEMIR, 85 (type 1 studies) and 363 (type 2 studies) were 65 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. In elderly patients with diabetes, the initial dosage, dose increments, and maintenance dosage should be conservative to avoid hypoglycemic reactions. Hypoglycemia may be difficult to recognize in the elderly.

ADVERSE REACTIONS
Adverse events commonly associated with human insulin therapy include the following:

Body as Whole: allergic reactions (see PRECAUTIONS, Allergy).

Skin and Appendages: lipodystrophy, pruritus, rash.

Mild injection site reactions occurred more frequently with LEVEMIR than with NPH human insulin and usually resolved in a few days to a few weeks (see PRECAUTIONS, Allergy).

Other:

Hypoglycemia: (see WARNINGS and PRECAUTIONS).

In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, the incidence of severe hypoglycemia with LEVEMIR was comparable to the incidence with NPH, and, as expected, greater overall in patients with type 1 diabetes (Table 4). Whether these observed differences represent true differences in the effects of LEVEMIR and NPH insulin is not known, since these trials were not blinded and the protocols (e.g., diet and exercise instructions and monitoring) were not specifically directed at exploring hypoglycemic related to weight effects of the treatments compared. The clinical significance of the observed differences has not been established.

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<tr>
<th>Type of Hypoglycemia</th>
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<th>Weight (kg)</th>
<th>Hypoglycemia (events/subject-month)</th>
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* Major = requires assistance of another individual because of neurologic impairment
** Minor = plasma glucose <56 mg/dl, subject able to deal with the episode him/herself.

OVERDOSAGE
Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure, or both. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. After apparent clinical recovery from hypoglycemia, continued observation and additional carbohydrate intake may be necessary to avoid reoccurrence of hypoglycemia.

More detailed information is available on request.

Rx only

Date of Issue: October 19, 2005

Manufactured for Novo Nordisk Inc., Princeton, NJ 08540

Manufactured by Novo Nordisk A/S, 2880 Bagsvaerd, Denmark

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program a hot topic for fiscal conservatives in Congress.

Such a projection may make it difficult to devise a replacement for the sustainable growth rate formula (SGR), which currently determines whether the Centers for Medicare & Medicaid Services raises or lowers physician pay each year. However, due to a quirk of the formula, the SGR dictates increasingly large cuts in the future, a situation that has led each year to Congress’s stepping in to set physician rates.

“Here we are in 2007; and for the past six years, every year we come down to the end of the year with the threat of a cut,” says Cecil Wilson, MD, chair of the American Medical Association’s board of trustees. “We have ended up working with Congress to get either a freeze, as we have the past couple of years, or maybe a one-percent increase. At this point, physician payments for Medicare are the same as they were in 2001.”

Both organized medicine and the Medical Payment Advisory Commission (MedPAC), an independent federal body that advises Congress on Medicare issues, have recommended expediency, mandating a rate increase for 2008 followed by a more permanent solution in the near future. While a fix will undoubtedly be expensive, a further delay will only add to the cost, MedPAC’s chair has told lawmakers.

Any solution will likely include measures designed to ensure that physicians provide Medicare enrollees with cost-effective, high-quality care. Lawmakers have called for proposals to make sure that, if the government is going to pay doctors more, the money will be used for funding efficient care. This is likely to mean more talk about reforms that dig deeper than a revamped SGR and even ramped-up pay-for-performance.

The Democratic Congress is also likely to spend some time debating changes to the Part D drug benefit, which was a costly
addition and has created some new headaches for physicians.

SGR and the Big Fix

The SGR formula is perhaps one of the most controversial aspects of Medicare. Over the past few years, it has been the subject of numerous congressional hearings, Capitol Hill rallies, and national surveys.

It didn’t start out that way.

“Back in 1997, when Congress wrote the SGR formula, for a few years it was okay,” says Paul Ginsburg, PhD, president of the Center for Studying Health System Change (known as HSC) in Washington, DC. Even when the formula first started taking a bite out of physician reimbursement, it didn’t cause much of a stir. “Physicians, in the early part of this decade, got some large increases; and in a sense it put them in okay shape to deal with a cut that came in 2002 and some years of lean increases,” he says.

The situation has changed considerably over the past few years. Part of the problem is that the formula was not designed to distinguish between appropriate and inappropriate growth in health spending. “It is one thing to have an incentive to control costs, but what they are grappling with is, what do you do when the goal is way beyond what is achievable?” says Dr. Ginsburg.

 “[The SGR] just assumes that all growth is bad growth,” says the AMA’s Dr. Wilson.

When the SGR was first being discussed in Congress, the initial idea was to link the spending increase to growth in the economy plus a couple of extra percentage points to allow for inflation in the cost of providing medical services. But by the time the legislation passed, the inflation adjuster had gotten stripped out. What was left was a formula that tracked growth of the economy but did not reflect changes in the cost of providing care.

“The SGR is based on how the economy is doing... The problem is that when patients get sick, they don’t decide to get sick when the economy is doing well and not get sick when the economy is not doing well,” Dr. Wilson says.

Physicians may have good reason to complain. Their pay rates are the only ones Medicare constrains by an SGR-like system. All other providers receive pay raises that are linked to the ris-
ing cost of health care. But to many physicians, it feels as if the SGR ensures that the more work they do, the less they get paid for each service they provide.

The AARP, which has launched a campaign to improve access to affordable health care, confirms that physicians’ rates have gone down as a result of the SGR. However, the organization points out that actual physician spending has increased under Medicare, presumably because physicians are providing additional services. Nevertheless, the influential organization supports replacing the SGR because it hasn’t done the job it was meant to do, i.e., contain the volume of physician services. Both the AMA and the AARP have recently signed on to the same piece of legislation designed to address the SGR, signaling that the two organizations see eye-to-eye on a potential solution, if not the problem.

But AARP is also troubled by the way organized medicine has chosen to draw attention to the problem of Medicare reimbursement. An organization spokesperson points to practices that inform patients they will no longer see Medicare patients. That’s a scary message for patients to hear, she says.

In May, the AMA released new survey findings showing that 60 percent of physicians say they will have to limit the number of new Medicare patients they see, if the 10-percent cut in reimbursement as expected under the SGR formula is not averted.

“We don’t know what will happen, but we fear that if draconian cuts do go through, it will create access problems for Medicare patients,” says the AMA’s Dr. Wilson.

The problem is bigger than just the number of Medicare patients a practice has, because on average, older patients need more care. Dr. Wilson points to his own practice as an illustration: “For my practice, about a third of my patients are in Medicare, but about two-thirds of the patients I see every day are Medicare, so a ten-percent cut would affect two-thirds of the practice,” he explains.

However, the flip side of that argument is that if Medicare makes up that much of a physician’s practice, it will be very difficult to give it up as a source of revenue. In fact, several surveys have shown that physicians are not dropping Medicare patients—not yet, at least.
Solutions Don’t Come Cheap

Any replacement of the current system will come with a hefty price tag.

“This is going to be expensive,” says Dr. Wilson. “Going by Congress’s accounting principles for this, they are going to have to come up with a lot of money. We’re talking about hundreds of billions of dollars. On the other hand, if it’s important enough, Congress usually finds the money.”

One way to help pay for it would be to cut the additional payments made to Medicare Advantage plans, which receive 112 percent of what Medicare’s traditional fee-for-service costs per patient.

“There’s no rhyme or reason to that,” Dr. Wilson says. “It’s an area that would free up some money that would help Congress and the Administration to try to find money to decrease the cost of this.”

MedPAC has also suggested that Congress level the playing field between the Medicare Advantage plans and fee-for-service rates. According to the government’s own estimate, eliminating that difference would save Medicare $54 billion over five years.

“The good news with where we are this year is that for the first time there is more discussion about that 12-percent extra that Medicare Advantage plans get, compared with fee-for-service,” says Dr. Wilson.

It’s a move that health insurers are likely to object to strongly, he says. “Obviously, Medicare Advantage plans won’t be enthusiastic about losing that differential.”

In May, the trade group, America’s Health Insurance Plans, announced that 100,000 seniors had enrolled in the Coalition for Medicare Choices, an advocacy group created to show support for Medicare Advantage plans. The coalition released survey results showing that 90 percent of the plans’ beneficiaries are satisfied with the coverage they are receiving.

The extra money the plans receive helps them offer additional services, thereby creating incentives for beneficiaries to try managed Medicare. It was never meant to be a permanent boondoggle, although some experts say it is too early to pull it away.

Congress has overridden the SGR formula for the past six years—usually at the last minute—but it’s the not-knowing that really bothers doctors. While a major cut in pay seems unlikely over the long run, even a one-year reduction could be seen by
many physicians as a harbinger of future cuts, impacting their willingness to accept new Medicare patients, Dr. Ginsburg says. “If it is just one more year, we’re going to fix it next year, then physicians probably won’t react as much,” he adds.

That is basically what physicians are asking for now. Based on MedPAC’s recommendations, the AMA and other medical groups have asked lawmakers to raise Medicare rates a mere 1.7 percent for next year with a promise to begin work on a more permanent remedy in 2008.

Other Acronyms of Concern

The problems with the SGR have also led people to thinking more about issues with the resource-based relative-value scale (RBRVS). That system was created to bring some order to payments among the various specialties. Work values were added several years ago to reflect the relative time spent delivering various services, adding another level of complexity.

The values are reviewed by the Relative Value Scale Update

Exploring Alternatives to the SGR Formula

There is no cheap way to replace the sustainable growth rate (SGR) formula, experts told senators during a hearing earlier this year.

The rising cost of health care is one of the biggest problems facing the government. At the current rate of growth, federal spending on Medicare and Medicaid will eventually consume 20 percent of the U.S. economy, says Peter Orszag, PhD, Director of the Congressional Budget Office (CBO). “In health care, we get what we provide incentives for. We currently provide lots of incentives for advanced technologies and high-end treatment, and we get a lot of that. We provide very little incentive for preventive medicine and get very little of that,” Dr. Orszag told lawmakers.

Last year, members of Congress asked the Medicare Payment Advisory Commission (MedPAC) to examine ways to reconfigure those incentives. MedPAC offered the lawmakers two alternative approaches: one that doesn’t include an SGR-like spending target and one that does. Eliminating spending targets altogether would require Congress to create a whole new system with incentives to physicians to provide high-quality and low-cost care. Choosing to keep spending targets would simplify payment reform, but would
Committee (RUC) every five years. During the most recent review, the committee agreed that, in the area of primary care, a general increase was needed to adjust for several years of falling reimbursement for evaluation and management services.

However, because of limits imposed by the SGR formula, that decision did not lead to an overall increase in payments to physicians. In order to maintain budget neutrality, CMS implemented an across-the-board cut that significantly diminished the increases for evaluation and management (E&M) codes and reduced the rates for all other services.

The RUC, which is a multi-specialty group, has focused on the science and has represented the medical community as a whole; but according to Dr. Wilson, there’s always a risk with a mechanism that benefits one group at the expense of another, that such comity will break down if there is not enough money for everybody.

HSC’s Dr. Ginsburg says this is a problem that has been building over time due to some substantial flaws in the relative-value system. “Over the years [RUC members] haven’t been doing still require changes to make the system more equitable. Neither remedy would come cheap. The CBO has estimated that current proposals will cost anywhere between $22 billion and $330 billion over the next ten years.

“There are lots of steps, including [health information technology] and comparative effectiveness, that offer at least the potential to bend that curve over the long term, but the cost savings may not show up in the next 10 years. That is just the way it is,” says Dr. Orszag. It will take time and resources to build a system in which Medicare puts the emphasis on high-value instead of high-cost services, he testified. “Given the scale of the problems that we face, we need to be trying lots of different things and recalibrating all the time,” he adds.

There are good ideas out there. The Centers for Medicare & Medicaid Services is the bottleneck, says MedPAC’s chairman, Glenn Hackbart, JD. “We’ve got some very promising demonstrations underway, but it takes us forever to get them developed, in place, gather results, and translate them into policy,” he testified. The agency doesn’t have the staff or information systems to move forward expeditiously, he adds.

“We’re trying to run the program on the cheap. That won’t work if we are trying to innovate at the same time,” says Mr. Hackbart.
their job to identify services that should have reductions in relative values. If they had been doing that, E&M would be in better shape,” he says.

While experts say the RUC has done a good job of holding down inappropriate increases, it rarely reduces payments for services that, as volume has increased, have become less expensive to deliver.

There have been proposals to revamp the relative value so that decreases in the cost of services are better accounted for as well as updated more frequently in order to more accurately reflect market changes. These changes are among a number of options being discussed to improve payment under Medicare, including care coordination, pay-for-performance, and medical home models.

Administrative Funds Fall Short

Another problem with the present Medicare system is that there isn’t funding to produce the kind of data the committee needs to make informed decisions.

“Specialty societies are going out and funding their own surveys because CMS does not have the funds to do one for all physicians... We’re talking about a few million dollars in a program that spends tens of billions every year,” says Dr. Ginsburg.

In general, Congress has failed to adequately fund the administrative side of Medicare. Because the program is an entitlement, the government has to provide whatever funds it needs to provide benefits to enrollees; but lawmakers decide how much money is available to CMS to administer that benefit.

“This is a very long-standing systemic issue. We are seeing more and more the consequences of having an underfunded CMS that can’t do the job,” says Dr. Ginsburg.

The Government Accountability Office periodically reports to Congress that increasing administrative funds could save Medicare money, but lawmakers have not yet heeded that message, says Dr. Ginsburg. “The situation stays the same year after year. Part of it is just turf within Congress. The appropriations committees want to hold onto their turf, but it makes for really bad policy,” he says.

Capitol Hill discussions about raising the pay for physicians are always accompanied by talk of improving the efficiency of
the Medicare program. “There is currently a great deal of interest in improving the efficiency of the Medicare program. This interest is driven not only by the desire to make Medicare a better program, but also by growing concern about the sustainability of Medicare spending,” Mark Miller, PhD, executive director of the MedPAC, told the House Energy and Commerce Committee in April.

Medicare has been hit by the same rapid rise in healthcare costs that has affected all payers. Medicare spending grew an average of 9.3 percent annually between 1980 and 2004, which is significantly faster than the average annual rate of growth in the gross domestic product of 6.5 percent during that period, he noted.

Over the past several years, MedPAC has recommended a number of strategies to improve efficiency in the program, including a payment fix that would improve accuracy, account for physician productivity, and identify when payments are too high. Another recommendation to Congress is to create larger units of payment, also known as bundling, to give physicians the ability to provide care efficiently while minimizing the temptation to increase profits by providing additional services.

Other recommendations include moving forward with pay-for-performance programs designed to provide incentives for high-quality, appropriate care; using Medicare administrative data to provide feedback to providers on how their service utilization compares with that of their peers; implementing payment incentives that promote care coordination models that have been shown to reduce adverse consequences such as avoidable hospitalizations; and setting up comparative effectiveness research projects to ensure that new healthcare treatments and technologies represent advances in quality or efficiency.

These changes would help ensure that Medicare is paying for
cost-effective, high-quality care, says Dr. Miller. “For three-quarters of the program’s existence, Medicare’s reimbursement for services was relatively indifferent to the quality of care provided. In general, as long as claims were submitted in accordance with applicable administrative and policy requirements, Medicare paid them,” he adds.

In its annual report on the state of the healthcare system, the American College of Physicians (ACP) also recommends bundling as one way that Medicare can improve the ability of physicians to provide efficient care. To that, they add risk adjustments so that physicians seeing the sickest patients are appropriately reimbursed for the additional work and expenses involved; fee-for-service payments for office visits so that prospective payments alone don’t create disincentives for physicians to see patients in their office; and a performance-based component for reporting on evidence-based quality, cost, and patient experience.

By undervaluing primary care, the current system discourages new physicians from entering primary care and practicing doctors from staying in the field, the ACP maintains. Meanwhile an aging population is increasing demand for care management and other primary care services. This will inevitably lead to “higher costs, lower quality, diminished access, and decreased patient satisfaction,” according to the ACP.

“The solution to such inadequacies is to redirect federal health-care policy toward supporting patient-centered health care that builds upon the relationship between patients and their primary and principal care physicians and supports the systems needed to achieve better results,” says ACP President Lynne Kirk, MD.

The College’s report recommends that the federal government take the lead in improving the nation’s healthcare system. “First, we are calling for Medicare to make fundamental changes in the way they pay physicians for delivering care. If our recommenda-
tions are accepted, Medicare would no longer pay physicians based solely on how many procedures or visits are billed,” says Robert Doherty, the College’s senior vice president for government affairs.

However, pay-for-performance and other instruments for imposing quality standards on physicians have their doubters as well. “For me, it’s hard to imagine Medicare getting pay-for-performance off the ground. There are so many technical problems for Medicare doing it...For example, for an enrollee, which physician do you attribute care to? That turns out to be a very hard job,” says HSC’s Dr. Ginsburg.

“Over the past year, the term ‘pay for performance’ has lost a lot of its meaning. It is such a popular term that it is being applied to a lot of things,” he adds.

Physicians are willing to undertake quality improvement initiatives, but would like to see them integrated into efforts to expand adoption of health information technology, says the AMA’s Dr. Wilson.

**Concerns About Medicare Part D**

While debate is expected to move forward in 2008, lawmakers may also have other Medicare questions on their plates. Although only a couple of years old, the Medicare drug benefit represents a big chunk of the Medicare budget, a fact likely to fuel discussion of ways to bring costs down.

Public advocacy groups have raised concerns about access barriers created by confusing rules that have left patients without their prescriptions. Doctors have had to deal with many of these problems directly, especially when patients come back with unfilled scripts. Proposals include giving CMS the ability to negotiate lower drug prices, reconfiguring the benefit to fill the doughnut hole (a gap in prescription coverage that affects some heavy users of the Medicare Part D program), and refining the rules to make the plans easier for patients to navigate.

Another concern is that the Medicare budget will trigger another warning, distracting lawmakers from reform efforts that could mean additional program spending. According to this year’s Medicare Trustee’s report, the future of Medicare funding looks pretty bleak.
TOPAMAX Tablets and TOPAMAX Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX in the acute treatment of migraine headache has not been studied. TOPAMAX is contraindicated in patients with a history of hypersensitivity to any component of this product.

IMPORTANT SAFETY INFORMATION

TOPAMAX has been associated with serious adverse events, including:

- Hyperchloremic, non-anion gap metabolic acidosis—lowering of bicarbonate levels in the blood. Measurement of baseline and periodic serum bicarbonate is recommended.
- Acute myopia and secondary angle-closure glaucoma—patients should be cautioned to seek medical attention if they experience blurred vision or ocular pain.
- Oligohidrosis and hyperthermia—decreased sweating and increased body temperature, especially in hot weather. The majority of reports have been in children.
- Cognitive/psychiatric side effects including cognitive dysfunction, psychiatric/behavioral disturbances including suicidal thoughts or behavior, and somnolence and fatigue.

Most common adverse events associated with TOPAMAX 100 mg vs placebo were: paresthesia, 51% vs 6%; anorexia,* 15% vs 6%; fatigue, 15% vs 11%; nausea, 13% vs 8%; diarrhea, 11% vs 4%; weight decrease, 9% vs 1%; taste alteration, 8% vs 1%.

The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products with TOPAMAX.

Patients should be instructed to maintain an adequate fluid intake in order to minimize the risk of renal stone formation.

*Anorexia is defined as loss of appetite.
MANAGING Migraines
MAY REQUIRE MORE THAN
A QUICK FIX.

Ask how frequent, disruptive migraines may impact her both during and between attacks. Choose TOPAMAX to help reduce migraine frequency.¹,²

Please see brief summary of full Prescribing Information on following pages.

References:

Life shouldn't always revolve around migraines.

TOPAMAX® (topiramate) (tablets)
www.topamax360.com

RX

Important
Avoid confusion with Toprol-XL® (metoprolol succinate) by spelling out TOPAMAX® (topiramate) on your prescription. Toprol-XL is a registered trademark of the AstraZeneca group of companies.
TOPAMAX® (topiramate) Tablets
TOPAMAX® (topiramate capsules) Sprinkle Capsules
Rx only
Brief Summary of Full Prescribing Information for Migraine.
CLINICAL STUDIES FOR OTHER INDICATIONS WILL HAVE DIFFERING ADVERSE EVENTS AND SAFETY CONCERNS. PLEASE SEE FULL PI FOR THIS INFORMATION REGARDING TOPAMAX® FOR EPILEPSY.

INDICATIONS AND USAGE
Migraine: TOPAMAX® (topiramate) Tablets and TOPAMAX® (topiramate capsules) Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX® in the acute treatment of migraine headache has not been studied.

CONTRAINDICATIONS: TOPAMAX® is contraindicated in patients with a history of hypersensitivity to any component of this product.

WARNINGS: Metabolic Acidosis: Hyperchloremic, non-anion gap, metabolic acidosis (i.e., decreased serum bicarbonate below the normal reference range in the absence of chronic respiratory alkalosis) is associated with topiramate treatment. This metabolic acidosis is caused by renal bicarbonate loss due to the inhibitory effect of topiramate on carbonic anhydrase. Such electrolyte imbalance has been observed with the use of topiramate in placebo-controlled clinical trials and in the post-marketing period. Generally, topiramate-induced metabolic acidosis occurs early in treatment although cases can occur at any time during treatment. Bicarbonate determinations are usually mild-moderate (average decrease of 4 mEq/L at daily doses of 400 mg in adults and at approximately 6 mg/kg/day in pediatric patients); rarely, patients can experience severe decrements to values below 10 mEq/L. Conditions or therapies that predispose to acidosis (such as renal disease, severe respiratory disorders, status epilepticus, diarrhea, surgery, ketogenic diet, or drugs) may be additive to the bicarbonate lowering effects of topiramate. Metabolic acidosis has been observed at doses as low as 50 mg/day. Serum bicarbonate levels have not been systematically evaluated at daily doses greater than 400 mg/day. The incidence of persistent treatment-emergent decreases in serum bicarbonate in placebo-controlled trials for adults for prophylaxis of migraine was 44% for 200 mg/day, 39% for 100 mg/day, 23% for 50 mg/day, and 7% for placebo. The incidence of a markedly abnormal serum bicarbonate (i.e., absolute decreases >17 mEq/L and drug-related reductions from pretreatment) in these trials was 11% for 200 mg/day, 9% for 100 mg/day, 2% for 50 mg/day, and <1% for placebo. Some manifestations of acute or chronic metabolic acidosis may include hyperventilation, nonspecific symptoms such as fatigue and anorexia, or more severe sequelae including cardiac arrhythmias or stupor. Chronic, untreated metabolic acidosis may increase the risk for nephrolithiasis or nephrocalcinosis, and may also result in osteomalacia (referred to as rickets in pediatric patients) and/or osteoporosis with an increased risk for fractures. Chronic metabolic acidosis in pediatric patients may also reduce growth rates. A reduction in growth rate may eventually decrease the maximal height achieved. The effect of topiramate on growth and bone-related sequelae has not been systematically investigated. Measurement of baseline and periodic serum bicarbonate during treatment is recommended. If metabolic acidosis develops and persists, consideration should be given to reducing the dose or discontinuing topiramate (using dose tapering). If the decision is made to continue patients on topiramate in the face of persistent acidosis, alkali treatment should be considered. Acute Myopia and Secondary Angle Closure Glaucoma: A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been reported in patients receiving TOPAMAX®. Symptoms include acute onset of decreased visual acuity, ocular pain. Ophthalmologic findings can include myopia, anterior chamber shallowing, ocular hyperemia (redness) and increased intraocular pressure. Mydriasis may or may not be present. This syndrome may be associated with supraciliary effusion resulting in anterior displacement of the lens and iris, with secondary angle closure glaucoma. Symptoms typically occur within 1 month of initiating TOPAMAX® therapy. In contrast to primary narrow angle glaucoma, which is rare under 40 years of age, secondary angle closure glaucoma associated with topiramate has been reported in pediatric patients as well as adults. The primary treatment to reverse symptoms and discontinuation of TOPAMAX® as rapidly as possible, according to the judgment of the treating physician. Other measures, in conjunction with discontinuation of TOPAMAX®, may be helpful. Elevated intraocular pressure of any etiology, if left untreated, can lead to serious sequelae including permanent vision loss. Oligohidrosis and Hyperthermia: Oligohidrosis (decreased sweating), infrequently resulting in hospitalization, has been reported in association with TOPAMAX® use. Decreased sweating and an elevation in body temperature above normal characterized these cases. Some of the cases were reported after exposure to elevated environmental temperatures. The majority of the reports have been in children. Patients, especially pediatric patients, treated with TOPAMAX® should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather. Caution should be used when TOPAMAX® is prescribed with other drugs that predispose patients to heat-related disorders; these drugs include, but are not limited to, other carbonic anhydrase inhibitors and drugs with anticholinergic activity. Cognitive/Neuropsychiatric Adverse Events: Adults: Adverse events most often associated with the use of TOPAMAX® were related to the central nervous system. In adults, the most frequent of these can be classified into three general categories: 1) Cognitive-related dysfunction (e.g., confusion, psychomotor slowing, difficulty with concentration/attention, difficulty with memory, speech or language problems, particularly word-finding difficulties); 2) Psychiatric/behavioral disturbances (e.g., depression or mood problems); and 3) Somnolence or fatigue. Cognitive-Related Dysfunction: The majority of cognitive-related adverse events were mild to moderate in severity, and they frequently occurred in isolation. Rapid titration rate and higher initial dose were associated with higher incidences of these events. Many of these events contributed to withdrawal from treatment (see ADVERSE REACTIONS, Table 1). In the 6-month migraine prophylaxis controlled trials using a slower titration regimen (25 mg/day weekly increments), the proportion of patients who experienced one or more cognitive-related adverse events was 19% for TOPAMAX® 50 mg/day, 22% for 100 mg/day, 28% for 200 mg/day, and 10% for placebo. These dose-related adverse reactions typically began in the titration phase and often persisted into the maintenance phase, but infrequently beyond the titration phase. Some patients experienced a recurrence of one or more of these cognitive adverse events and this recurrence was typically in the titration phase. A relatively small proportion of topiramate-treated patients experienced more than one concurrent cognitive adverse event. The most common cognitive adverse events occurring together included difficulty with memory along with difficulty with concentration/attention, difficulty with memory along with language problems, and difficulty with concentration/attention along with language problems. Rarely, topiramate-treated patients experienced three concurrent cognitive events. Psychiatric/Behavioral Disturbances: Psychiatric/behavioral disturbances (depression or mood problems) were dose-related for both the epilepsy and migraine populations. In the double-blind phases of clinical trials with topiramate in approved and investigational indications, suicide attempts occurred at a rate of 3/1000 patient years (13 events/3999 patient years) on topiramate versus 0 (0 events/1430 patient years) on placebo. One completed suicide was reported in a bipolar disorder trial involving a patient on topiramate. Somnolence/Fatigue: Fatigue and somnolence were dose-related and more common in the titration phase. PRECAUTIONS: Hyperammonemia and Encephalopathy Associated with Concomitant Valproic Acid Use: Concomitant administration of topiramate and valproic acid has been associated with hyperammonemia with or without encephalopathy in patients who have tolerated either drug alone. Clinical symptoms of hyperammonemic encephalopathy often include...
as in the general population, the incidence of 

Kidney Stones have also been reported in pediatric patients. The concomitant 

Physiological environment that increases the risk of kidney stone formation among topiramate treated patients was higher in patients with reduced renal function (see PRECAUTIONS: In renal Failure). The clinical relevance of this observation has not been established. Kidney Stones: As in the general population, the incidence of stone formation among topiramate treated patients was higher in men. Kidney stones have also been reported in pediatric patients. An explanation for the association of TOPAMAX® and kidney stones may lie in the fact that topiramate is a carbonic anhydrase inhibitor. Carbonic anhydrase inhibitors, e.g., acetazolamide or dichlorphenamide, promote stone formation by reducing urinary citrate excretion and by decreasing urinary pH. The concomitant use of TOPAMAX® with other carbonic anhydrase inhibitors or potentially in patients on a ketogenic diet may create a physiological environment that increases the risk of kidney stone formation, and should therefore be avoided. Increased fluid intake increases the urinary output, lowering the concentration of substances involved in stone formation. Hydration is recommended to reduce new stone formation. Paresthesia: Paresthesia (usually tingling of the extremities), an effect associated with the use of other carbonic anhydrase inhibitors, appears to be a common effect of TOPAMAX®. Paresthesia was more frequently reported in the monotherapy epilepsy trials and migraine prophylaxis trials versus the adjunctive therapy epilepsy trials. In the majority of instances, paresthesia did not lead to treatment discontinuation. Adjustment of Dose in Renal Failure: The renal route of elimination of unchanged topiramate metabolites is via the kidney. Dosage adjustment may be required in patients with reduced renal function (see DOSAGE AND ADMINISTRATION in the full PI). Decreased Hepatic Function: In heptatically impaired patients, topiramate should be administered with caution as the clearance of topiramate may be decreased. Information for Patients: Patients should be instructed to read the Patient Information before starting treatment with TOPAMAX® and each time their prescription is renewed. Patients taking TOPAMAX® should be told to seek immediate medical attention if they experience blurred vision, visual disturbances or periorbital pain. Patients taking TOPAMAX® should be monitored closely for evidence of decreased sweating and increased body temperature, especially in hot weather. Patients, particularly those with predisposing factors, should be instructed to maintain an adequate fluid intake in order to minimize the risk of renal stone formation. Drug Interactions: In vitro studies indicate that topiramate does not inhibit enzyme activity for CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP2E1 and CYP3A4/5 isozymes. Other Drug Interactions: Dignoxin: In a single-dose study, serum digoxin AUC was decreased by 12% with concomitant TOPAMAX® treatment. The clinical relevance of these findings has not been established. CNS Depressants: Concomitant administration of TOPAMAX® and alcohol or other CNS depressant drugs has not been evaluated in clinical studies. Because of the potential of topiramate to cause CNS depression, as well as other cognitive and/or neuropsychiatric adverse events, topiramate should be used with extreme caution if used in combination with alcohol and other CNS depressants. Oral Contraceptives: In a pharmacokinetic interaction study in healthy volunteers, concomitantly administered combination oral contraceptive product containing 1 mg norethindrone (NET) plus 35 mcg ethinyl estradiol (EE), TOPAMAX® given in the absence of other medications at doses of 50 to 200 mg/day was not associated with statistically significant changes in mean exposure (AUC) to either component of the oral contraceptive. In another study, exposure to EE was statistically significantly decreased at doses of 200, 400, and 800 mg/day (18%, 21%, and 30%, respectively) when given as adjunctive therapy in patients taking valproic acid. In both studies, TOPAMAX® (50 mg/day to 800 mg/day) did not significantly affect exposure to NET. Although there was a dose dependent decrease in EE exposure for doses between 200-800 mg/day, there was no significant dose dependent change in EE exposure for doses of 50-200 mg/day. The clinical significance of the changes observed is not known. The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products of kidney stones or other contraindications to a ketogenic diet. Topiramate should be administered with caution as the clearance of topiramate may be decreased when administered with HCTZ. The extent of change in the clearance is unknown. The clinical significance of the effect of topiramate on oral contraceptive pharmacokinetics is unclear. Oral plasma clearance of topiramate appears to be reduced when administered with metformin. The extent of change in the clearance is unknown. The clinical significance of the effect of metformin on topiramate pharmacokinetics is unclear. When TOPAMAX® is added or withdrawn in patients on metformin therapy, careful attention should be given to the routine monitoring for adequate control of their diabetic disease state. Pioglitazone: A drug-drug interaction study conducted in healthy volunteers evaluated the steady-state pharmacokinetics of metformin and pioglitazone in plasma when metformin was given alone and when metformin and pioglitazone were given simultaneously. The results of this study indicate that metformin Cmax increased by 27% and AUC increased by 29% when HCTZ was added to topiramate. The clinical significance of this change is unknown. The addition of HCTZ to topiramate therapy may require an adjustment of the topiramate dose. The concomitant administration of HCTZ was not significantly influenced by the concomitant administration of topiramate. Clinical laboratory results indicated decreases in serum potassium after topiramate or HCTZ administration, which were greater when HCTZ and topiramate were administered in combination. Metformin: A drug-drug interaction study conducted in healthy volunteers evaluated the steady-state pharmacokinetics of metformin and pioglitazone in plasma when metformin was given alone and when metformin and topiramate were given simultaneously. The results of this study indicated that metformin mean Cmax and mean AUC0-12h increased by 18% and 25%, respectively, while mean Cmax and mean AUC0-12h were reduced by 60% and 25% respectively when pioglitazone was co-administered with topiramate. Topiramate did not affect metformin t1/2. The clinical significance of the effect of topiramate on metformin pharmacokinetics is unclear. Oral plasma clearance of topiramate appears to be reduced when administered with metformin. The extent of change in the clearance is unknown. The clinical significance of the effect of metformin on topiramate pharmacokinetics is unclear. When TOPAMAX® is added or withdrawn in patients on metformin therapy, careful attention should be given to the routine monitoring for adequate control of their diabetic disease state.
adults (6 M, 7 F). Amitriptyline: There was a 12% increase in AUC and Cmax for amitriptyline (25 mg per day) in 18 normal subjects, whether they were male or female and of any age or weight. Some subjects may experience a large increase in amitriptyline concentration in the presence of topiramate and any adjustments in amitriptyline dose should be made according to the patient’s clinical response and not on the basis of plasma levels. Sumatriptan: Multiple dosing of topiramate (100 mg every 12 hrs) in 24 healthy volunteers (14 M, 10 F) did not affect the pharmacokinetics of single dose sumatriptan either orally (100 mg) or subcutaneously (6 mg). Risperidone: There was a 25% decrease in exposure to risperidone (2 mg single dose) in 12 healthy volunteers (6 M, 6 F) receiving 200 mg/day of topiramate. Therefore, patients receiving risperidone in combination with topiramate should be closely monitored for clinical response. Propranolol: Multiple doses of topiramate (200 mg/day) in 34 healthy volunteers (17 M, 17 F) did not affect the pharmacokinetics of propranolol following daily 160 mg doses. Propranolol doses of 160 mg/day in 39 volunteers (27M, 12F) had no effect on the exposure to topiramate at a dose of 200 mg/day of topiramate. Dihydroergotamine: Multiple dosing of topiramate (200 mg/day) in 24 healthy volunteers (12 M, 12 F) did not affect the pharmacokinetics of a 1 mg subcutaneous dose of dihydroergotamine. Similarly, a 1 mg subcutaneous dose of dihydroergotamine did not affect the pharmacokinetics of a 200 mg/day dose of topiramate in the same study. Others: Concomitant use of TOPAMAX®, a carbonic anhydrase inhibitor, with other carbonic anhydrase inhibitors, anticonvulsants or antihypertensives may create a physiological environment that increases the risk of renal stone formation, and should therefore be avoided. Drug/Laboratory Tests Interactions: There are no known interactions of topiramate with commonly used laboratory tests. Carcinogenesis, Mutagenesis, Impairment of Fertility: An increased frequency of limb malformations (ectrodactyly, micromelia, and amelia) was increased among the offspring of dams treated with dihydroergotamine (400 mg/kg (10 times the Rhd on a mg/m2 basis) or greater) during organogenesis; embryo/fetal mortality was increased at 35 mg/kg (2 times the Rhd on a mg/m2 basis) or greater, and teratogenic effects (primarily rib and vertebral malformations) were observed at 120 mg/kg (6 times the Rhd on a mg/m2 basis). Evidence of maternal toxicity (decreased body weight gain, clinical signs, and/or maternal body weight gain at ≥35 mg/kg) and/or fetotoxicity (decreased body weight gain, clinical signs) was evident at 100 mg/kg or greater. In a rat embryo/fetal development study with a postnatal component (0.2, 2.5, 30, or 400 mg/kg during organogenesis; noted above), pups exhibited decreased physical development at 400 mg/kg (5 times the Rhd on a mg/m2 basis) and reductions in pre- and/or postweaning body weight gain at 2 mg/kg (0.05 times the Rhd on a mg/m2 basis) and above. Maternal toxicity (decreased body weight gain, clinical signs) was evident at 100 mg/kg or greater. In a rat embryo/fetal development study with a postnatal component (0.2, 2.5, 30, or 400 mg/kg during organogenesis; noted above), pups exhibited delayed physical development at 400 mg/kg (10 times the Rhd on a mg/m2 basis) and persistent reductions in body weight gain at 30 mg/kg (1 times the Rhd on a mg/m2 basis) and higher. There are no studies using TOPAMAX® in pregnant women. TOPAMAX® should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. In post-marketing experience, cases of hypospadias have been reported in male infants exposed in utero to topiramate, with or without other anticonvulsants; a relationship with topiramate exposure has not been established. Labor and Delivery: In studies of rats where dams were allowed to deliver pups naturally, no drug-related effects on gestation length or parturition were observed at dosage levels up to 200 mg/kg/day. The effect of TOPAMAX® on labor and delivery in humans is unknown. Nursing Mothers: Topiramate is excreted in the milk of lactating rats. The excretion of topiramate in human milk has not been evaluated in controlled studies. Limited observations in patients suggest an extensive secretion of topiramate into breast milk. Since many drugs are excreted in human milk, and because the potential for serious adverse reactions in nursing infants outweighs the potential benefit to the mother should be weighed against the potential risk to the infant when considering recommendations regarding nursing. Pediatric Use: Topiramate is associated with metabolic acidosis. Chronic untreated metabolic acidosis in pediatric patients may cause osteomalacia/rickets and may reduce growth rates. A reduction in growth rate may eventually decrease the maximally tolerated dose. The effect of topiramate on growth and bone-related sequelae has not been systematically investigated (see WARNINGS). Safety and effectiveness in pediatric patients have not been established for the prophylaxis treatment of migraine headache. Geriatric Use: In clinical trials, 3% of patients were over 60. No age-related differences in safety or effectiveness were evident. However, clinical studies of topiramate did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. Dosage adjustment may be necessary for elderly patients with impaired renal function (creatinine clearance rate ≤50 mL/min/1.73 m2) due to reduced clearance of topiramate (see CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION in the full PI). Race and Gender Effects: Evaluation of effectiveness and safety in clinical trials has shown no race or gender related effects. ADVERSE REACTIONS: The data described in the following section were obtained using TOPAMAX® (topiramate) Tablets. Migraine: In the four multicenter, randomized, double-blind, placebo-controlled, parallel group migraine prophylaxis clinical trials, most of the adverse events with topiramate were mild or moderate in severity. Most adverse events occurred more frequently during the titration period than during the maintenance period. Table 1 includes those adverse events reported for patients in the placebo-controlled trials where the incidence rate in any topiramate treatment group was at least 2% and was greater than that for placebo patients. Table 1: Incidence of Treatment-Emergent Adverse Events in Placebo-Controlled, Migraine Trials Where Rate Was ≥ 2% in Any


**Topiramate Group and Greater than the Rate in Placebo-Treated Patients.**

**Body System/Adverse Event followed by Placebo (N=445) first, TOPAMAX® Dosage (mg/day) second, 100 (N=386) third, 200 (N=514) fourth. Body as a Whole – Central Nervous System Disorders:** Parasthesia 6, 35, 51, 49; Dizziness 10, 8, 9, 12; Hypoesthesia 2, 6, 7, 8; Language Problems 2, 7, 6, 7; Involuntary Muscle Contractions 1, 2, 4, 4; Ataxia 1, 1, 2, 2; Fever Disorders/Related Speech Problems <1, <1, <1, <1; Gastro-Intestinal System Disorders:** Nausea 8, 9, 13, 14; Diarrhea 4, 9, 11, 11; Abdominal Pain 5, 6, 7, 7; Dyspepsia 3, 4, 5, 3; Gastro-Intestinal System Disorders:** Dry Mouth 2, 2, 3, 5; Vomiting 1, 2, 2, 2; Gastroenteritis 0, 0, 3, 0; Hearing and Vestibular Disorders:** Tinnitus 1, <1, 1, 2; Metabolic and Nutritional Disorders:** Weight Decrease 1, 6, 9, 11; Thirst <1, 1, 2, 2; Musculoskeletal System Disorders:** Arthralgia 2, 7, 3, 1; Neoplasms:** Neoplasm NOS <1, 2, <1, <1; Psychiatric Disorders:** Anorexia 6, 9, 15, 14; Somnolence 5, 8, 7, 10; Difficulty with Memory NOS 2, 7, 7, 11; Difficulty with Concentration/Attention 2, 3, 6, 10; Insomnia 5, 6, 7, 6; Anxiety 3, 4, 5, 6; Mood Problems 2, 3, 6, 5; Depression 4, 3, 4, 6; Nervousness 2, 4, 4, 4; Confusion 2, 2, 3, 4; Psychomotor Slowing 1, 3, 2, 4; Libido Decreased 1, 1, 1, 2; Aggravated Depression 1, 1, 2, 2; Agitation 1, 2, 2, 1; Cognitive Problems NOS 1, <1, <1, <1; Reproductive Disorders, Female:** Menstrual Disorder 2, 3, 2, 2; Reproductive Disorders, Male:** Ejaculation Premature 0, 0, 0, 0; Resistance Mechanism Disorders:** Viral Infection 3, 4, 4, 3; Otitis Media <1, 1, 2, 1; Respiratory System Disorders:** Upper Respiratory Tract Infection 12, 2, 13, 14; Sinusitis 6, 10, 6, 8; Pharyngitis 4, 5, 6, 2; Coughing 2, 2, 4, 4; Bronchitis 2, 3, 3, 3; Dyspnea 2, 1, 3, 2; Rhinitis 1, 1, 2, 2; Skin and Appendages Disorders:** Rhinitis 0, 0, 1, 1; Coughing 2, 2, 4, 3; Bronchitis 2, 3, 3, 3; Upper Respiratory Tract Infection 12, 3, 14, 14; Skin and Appendages Disorders:** Rhinitis 1, 1, 2, 2; Coughing 2, 2, 4, 3; Bronchitis 2, 3, 3, 3; Skin and Appendages Disorders:** Skin Rash, alopecia.

**Gastrointestinal System Disorders:** Abdominal pain, nausea, vomiting, diarrhea, weight decrease, difficulty with concentration/attention, and somnolence.

**Drug Abuse and Dependence:** The abuse and dependence potential of TOPAMAX® has not been evaluated in human studies.

**OVERDOSAGE**

Overdoses of TOPAMAX® have been reported. Signs and symptoms included convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness and depression. The clinical consequences were not severe in most cases, but deaths have been reported after polydrug overdoses involving TOPAMAX®

Topiramate overdose has resulted in severe metabolic acidosis (see WARNINGS).

A patient who ingested a dose between 96 and 110 g topiramate was admitted to hospital with coma lasting 20-24 hours followed by full recovery after 3 to 4 days.

In acute TOPAMAX® overdose, if the ingestion is recent, the stomach should be emptied immediately by lavage or by induction of emesis. Activated charcoal has been shown to adsorb topiramate in vitro. Treatment should be appropriately supportive. Hemodialysis is an effective means of removing topiramate from the body.

**Table 2: Incidence (%) of Dose-Related Adverse Events From Placebo-Controlled, Migraine Trials.**

**Adverse Event followed by Placebo (N=445) first, TOPAMAX® Dosage (mg/day) second, 100 (N=386) third, 200 (N=314) fourth. Body as a Whole – Central Nervous System Disorders:** Parasthesia 6, 35, 51, 49; Dizziness 11, 14, 15, 19; Nausea 8, 9, 13, 14; Anorexia 6, 9, 15, 14; Dizziness 10, 8, 9, 12; Weight decrease 1, 6, 9, 11; Difficulty with Memory NOS 2, 7, 7, 11; Diarrhea 4, 9, 11, 11; Difficulty with Concentration/Attention 2, 3, 6, 10; Somnolence 5, 8, 7, 7; Hypoesthesia 2, 6, 7, 8; Anxiety 3, 4, 5, 6; Depression 4, 3, 4, 6; Mood Problems 2, 3, 6, 5; Dry Mouth 2, 2, 3, 5; Confusion 2, 2, 3, 4; Involuntary Muscle Contractions 1, 2, 2, 4; Abnormal Vision <1, 1, 2, 2; Renal Calculus 0, 0, 1, 2.* The incidence rate of the adverse event in the 200 mg/day group was ≥ 2% than the rate in both the placebo group and the 50 mg/day group.
However one defines them, pay-for-performance efforts are unlikely to succeed if they don’t seek input from physicians. That is the stance of several organizations involved in discussion of the concept.

“Physicians are very hungry for information about how they perform relative to their peers,” says David Lee, MD, vice president of Healthcare Management for Anthem Blue Cross Blue Shield of Indiana. However, programs have to be rolled out in collaboration with physicians in order for them to gain acceptance, especially if the programs have the potential to move the system away from volume-based payment.

Physician groups such as the American Medical Association and the Medical Group Management Association generally support performance-rating programs as long as they are voluntary and primarily designed to improve the quality and safety of health care.

In June, the AMA adopted a policy to oppose performance-rating efforts that do not put patients first. “Those pay-for-performance programs whose only goal is to save money for health plans will not be tolerated,” says board member J. James Rohack, MD.

Anthem has conducted a number of pilot programs over the past couple of years. Through that experimentation, the insurer has learned that claims data alone don’t provide a useful approach for assessing quality of care. “You really need clinical information to have a complete picture of the care the physician is rendering. The corollary to that is that it is very difficult to get that clinical information from physicians; it’s just one more administrative hassle,” says Dr. Lee.

Fragmentation of the healthcare system is another hurdle for these efforts, he says. “The typical physician, seeing a patient in the exam room, particularly if the patient has commercial coverage, generally does not know the carrier for that patient, let alone what quality incentive or metric or program that carrier is espousing,” he says.

That also means plans pose a greater challenge in feeding useful information back to the doctors. For example, Anthem Blue Cross Blue Shield makes up about 25 percent to 30 percent of the commercial health insurance market share in Indiana. While that represents a large number of insureds, it is still difficult for the insurer to dictate major-scale changes in the way physicians manage their practices. “When you add Medicare and Medicaid into the mix, we really only make up 10 to 15 percent of the typical physician’s practice; and that is just not enough scale for physicians to make big changes in their practice.
processes," says Dr. Lee.

However, there may be a lesson in these efforts for the government as well. According to a Government Accountability Office (GAO) report released in April, Medicare already has substantial data on hand that could be used to evaluate physician efficiency. Assets available to the program include CMS centralized repository of medical claims, the sheer size of the program, and the ability to use established risk-adjustment mechanisms to compensate for patient health status. There are also lessons from the private sector in how to use that information to improve efficiency.

"Some healthcare purchasers seek to curb inefficient practices through physician education and other measures directed at physicians' income—such as discouraging patients from obtaining care from physicians whom the purchaser, through profiling, ranks as inefficient. If similar approaches were adopted in Medicare—that is, profiling physicians for efficiency and strategically applying the results—the experience of other purchasers suggests that reductions in spending growth could be achieved," the report concludes.

However, for Medicare to do this, it may need additional authorities granted by Congress, the GAO stated.

The program may also have to overcome the objections of physicians. Early attempts at pay-for-performance have helped foster a sense of distrust between many physicians and payers, says Dr. Lee. "Among physicians receiving a quality report from a payer that assesses their overall quality of care, especially when reimbursement is tied to that quality report, well, let's just say there is a certain degree of skepticism," he says.

At the April annual meeting of the American College of Physicians, the group adopted a policy paper requesting that physicians be given the opportunity to review and comment on performance ratings before they are made public. The 11-point policy paper comes on the heels of complaints from physicians that several early attempts to rate physicians' performance have either failed to take into account the variation in patient mix between practices or contained technical mistakes without any mechanism for correcting them. Recent press reports suggest that health plans have been terminating physician contracts due to such glitches.

"A fair and accurate reconsideration process is yet another way to minimize unintended consequences that may compromise the care of patients," says ACP President Lynne Kirk, MD.
“Medicare’s Hospital Insurance (HI) Trust Fund is already expected to pay out more in hospital benefits this year than it receives in taxes and other dedicated revenues,” the trustees write. “In addition, the Medicare Supplementary Medical Insurance (SMI) Trust Fund that pays for physician services and the new prescription drug benefit will continue to require general revenue financing and charges on beneficiaries that grow faster than the economy and beneficiary incomes over time.”

This year marks the first time that the budget outlook has triggered a “Medicare Funding Warning,” a signal that within the next seven years the program will be drawing more than 45 percent of its dollars from general revenues rather than the trust fund. The warning was mandated as part of the Medicare Modernization Act passed in 2003, which also requires that, following a second consecutive warning, the President submit a proposal to Congress on how to bring that spending down.

Some experts question whether this red flag is a red herring. “This threshold is misguided: Medicare is supposed to be financed in significant part with general revenues. That at least 45 percent of Medicare will be financed with general revenues is no more a problem than that 100 percent of defense, education, or most other federal programs is financed with general revenues,” according to a statement from Robert Greenstein, executive director of the Center for Budget and Policy Priorities, a Washington, DC, think tank.

It is not clear that the warning is an appropriate indicator of lack of control in the program. While there have been studies that conclude that Medicare’s growth outpaces rates in the private marketplace, others suggest that it hasn’t done so.

“Be very skeptical about the various studies that have tried to determine whether Medicare, on a per-enrollee basis, is growing faster or slower than private insurance. The real answer is that they are growing about the same rate because they are drawing on the same medical care system,” says HSC’s Dr. Ginsburg.
they are growing about the same rate because they are drawing on the same medical care system,” says HSC’s Dr. Ginsburg.

**Medicare Comes Knocking**

One Medicare cost-saving initiative that has not had much of a public airing, but has many doctors venting, is recovery audits conducted by private firms at Medicare’s behest. Since March 2005, such firms have been conducting audits in California, Florida, and New York, seeking out erroneous payments to physicians, hospitals, and other providers. During the demonstration period, the Medicare recovery audits collected $64.6 million in overpayments and identified another $224.5 million in potential recoveries. The firms have also identified $10.4 million in underpayments.

Over the objections of the AMA and organized medicine in general, when lawmakers passed a last-minute bill to fix the physician reimbursement rate under Medicare for 2007, they included a provision requiring the CMS to expand the audit program to all 50 states by 2010.

So far, the bulk of the money identified through the audits represents payments to inpatient hospitals. However, audit contractors have also identified nearly $18 million in potential overpayments to physicians and other providers. In California and New York, contractors have chosen to focus mainly on auditing hospitals and nursing facilities. But the contractor in Florida, a company called Health Data Insights based in Nevada, chose to concentrate on physicians’ offices.

Most physicians are already familiar with two kinds of audits Medicare conducts, one based on red flags signaled during the normal claims processing, and the other based on random audits of small samples of providers. “Now you are adding in a third type of audit, which is substantially different from what Medicare has done in the past,” says W. Fred Whitson, JD, Director of Medical Economics at the Florida Medical Association.

One difference is that the audits are conducted on all physician claims in the states and can include records as far back as four years. Another difference is that, because the firms are paid on contingency, physicians in Florida have come to think of them as bounty hunters.
“Our docs don’t like it,” says Mr. Whitson. Recovery audit contractors “don’t get paid unless they find something. Therefore they’ve got a lot of incentive to really dig and find things.”

While perhaps a tenuous silver lining, the good news is that despite all that digging, the average demand letter is only $135. “That means they are not finding a lot wrong with the physicians,” he says.

The bad news is that most physicians don’t have time to fight contractors over such a small amount. “It’s cheaper to pay the $135 than to go back and dig out those files, which might be in some warehouse somewhere, and try to figure out did I really overcharge,” he explains. However, this willingness to settle may be giving those who oversee the program the false impression that contractors are more successful at identifying overpayments than they really are, he adds.

There have also been problems with the initial design of the program, he says. “Initially, the program identified only overpayments. When we got involved with this in the latter part of 2004, we said, ‘Wait a minute, that’s not fair if they’re looking at 100 percent of the data and not correcting underpayments as well as overpayments,’” says Mr. Whitson. After a lot of work on the part of the association, CMS agreed to pay the contractor the same contingency fee for identifying underpayments. However, that rule change was not applied retroactively.

The association has also found that appeals were slanted against physicians. Once a physician gets a demand letter, he or she has 30 days to pay or appeal before the overpayment amount begins accruing interest and Medicare starts deducting it from future reimbursement. Originally those measures would kick in even if the physician were in the process of appealing the
demand letter; but FMA was able to get CMS to change the policy to delay the deduction until after the appeal was completed, though interest would still accrue.

For physicians who find themselves on the receiving end of an audit, the key to fighting it is to provide any information that backs up the claim. That means when responding to a demand letter, physicians should send not just the patient records for the day of services but any other records that relate to whatever treatments, tests, or services were provided. Physicians should also use a cover letter to fill in any gaps or leaps of logic that might help explain their medical decisions and coding choices, says Paul Cirel, JD, a partner with Dwyer & Collora, LLP, in Boston.

Medical records are typically organized in a specific way, with laboratory results in one place, comments from referring physicians in another. When a procedure requires a referral, or when a laboratory test is necessary, physicians should make sure to include those documents as well, says Mr. Cirel, cautioning physicians not to simply photocopy one page and send it off to the auditor. “It’s very easy for them to say there’s no documentation for the labs, because you didn’t send any,” he says.

Mr. Cirel strongly advises physicians against adding anything to their records after the fact. “You can write Crime and Punishment in a cover letter... but you don’t change or alter the medical record,” he warns.

Although the program has so far identified nearly 18 million in overpayments to physicians and other small providers, the companies have collected only $3.2 million. In Florida alone, more than 1,400 physicians are in the process of appealing demand letters.